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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,328	07/22/2003	John McMichael	13024/38627A	6971

4743 7590 11/01/2007
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EXAMINER

HUGHES, ALICIA R

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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11/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/624,328
Filing Date: July 22, 2003
Appellant(s): MCMICHAEL ET AL.

MAILED
NOV 01 2007
GROUP 1600

Jeffrey S. Sharp

For Appellant

EXAMINER'S ANSWER

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This is in response to the appeal brief filed 09 October 2007 appealing from the Office action mailed 22 January 2007.

1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

U.S. Patent Application Publication No. 2003/0072793

Frey et al

U.S. Patent No. 5,599,560

Siuciak

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The Merck Manual of Diagnosis and Therapy, 17th Edition, Merck Manual
pp. 1525-1539 and 1932-1933 (1999).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 1,2,4,5,8-18, and 20-24 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent Application Publication No. 2003/0072793 AL [hereinafter referred to as "Frey II, et al."] in view of Beers, M.H. and Berkow, R., Editors-in-Chief, THE MERCK MANUAL OF DIAGNOSIS AND THERAPY, 17th Edition, pages 1525-1539 and 1932-1933, 1999 [hereinafter referred to as "The Merck Manual"].

Frey II, et al teach the administration of nerve growth factor ["NGF"] for the treatment of disorders or diseases of the central nervous system (Paragraphs 50, 51, and 169). In addition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The prior art reference of Frey II, et al teaches the using of "preferred neurologic agents," namely growth factors such as nerve growth factor (See paragraph 51). Frey II, et al also teach the treatment of central nervous system disorders, particularly affective

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disorders and anxiety disorders (Paragraph 169). Frey II et al also teach various well-known forms of administration, such as sublingual administration (Paragraph 121), buccal and topical administration (Paragraph 123) as well as parenteral formulations and other formulations known in the art (Paragraphs 122 and 124-126).

The Merck Manual discloses that the definition of depression (a unipolar) disorder falls under a broad class of mood or affective disorders (Page 1525). The Merck Manual also states that individuals with mixed anxiety-depression possess conditions of symptoms that have both anxiety and depression (page 1529) and that depressed patients are anxious and depressed, typically (page 1531). The Merck Manual specifically discloses to the skilled artisan that a patient with the condition of premenstrual syndrome ["PMS"] is characterized, *inter alia*, by anxiety and depression (page 1932).

Although Frey II, et al is silent to the use of NGF to treat the psychological conditions of PMS, anxiety disorders, and panic attacks, Frey II, et al do in fact teach and provide the artisan with the necessary motivation to use nerve growth factor in the treatment of affective and anxiety disorders (Paragraph 169). Accordingly, one having ordinary skill in the art would have recognized that by treating depression and anxiety, one would also be treating and alleviating the symptoms of related conditions and ailments that have depression and anxiety as symptoms, namely anxiety disorders, PMS, and depression associated with menstruation and anxiety associated with panic attacks, most especially in view of the teaching of the Merck Manual.

Moreover, the determination of a specific range of a dosage having the optimum therapeutic index is well within the level of knowledge of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the

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maximum effect of the drug while minimizing unwanted and/or adverse side effects as a matter of general practice. Hence, Frey II, et al in view of the Merck Manual make obvious the claimed subject matter.

In traversing the above rejection, Appellants argue that the Board should reverse the final rejection, because: (1) Frey II, et al. discloses a laundry list of agents for the treatment of a laundry list of diseases, but does not teach explicitly that nerve growth factor ["NGF"] can be utilized to treat symptoms of psychological disorders; (2) the Merck Manual does not overcome the deficiency in Frey II, et al, because the Merck Manual neither teaches nor suggests the use of NGF for the treatment of any disease, let alone for the treatment of psychological disorders disclosed in the contemplated invention; and (3) the only motivation or suggestion to combine Frey II, et al with the Merck Manual to alleviate the symptoms of psychological disorders arises from disclosures of the present invention and therefore, constitute impermissible hindsight.

Appellee agrees that Frey, II et al is a broad patent that discloses numerous agents to treat a number of disease and conditions. However, the breadth of Frey II, et al is inadequate justification for why the disclosure of the invention in the instant application is not obvious, particularly in view of the Merck Manual's disclosure that depression, for example, falls under a broad class of mood or affective disorders.

Importantly, Frey II, et al, was a filed patent application on the date to which Appellants claim priority, and Frey II, et al discloses among other things, the administration of NGF to treat affective disorders and other diseases and disorders of the central nervous system. Therefore, the administration of NGF to treat central nervous system diseases and conditions was known in the art at the time the presently

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contemplated application was filed. Appellants “[r]eading a list and selecting a known compound to meet known requirements in no more ingenious than selecting the last piece to put in the last opening of a jigsaw puzzle.” *Sinclair & Carroll Co.*, 325 U.S. at 335. More particularly, NGF is listed in *Frey II, et al.* as an agent to treat among other things, diseases of the central nervous system, inclusive of psychological disorders, which are disclosed in the Merck Manual.

The requisite motivation to combine references is present, because although *Frey II, et al.* is silent as to the use of NGF to treat the psychological conditions of PMS, and panic attacks, explicitly, the same does teach the preferred use of NGF to treat affective disorders and anxiety disorders. The Merck Manual merely defines affective and anxiety disorders more clearly to include the alleviation of symptoms of related conditions and ailments that have depression and anxiety as symptoms, namely anxiety disorders, PMS and panic attacks.

In view of the foregoing, the rejection that claims 1,2,4, 5, 8-18, and 20-24 are obvious over *Frey II, et al.* in view of the Merck Manual should be sustained.

B. Claims 1,2,4,5,11-15, and 20-24 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,599,560 [hereinafter referred to as “Siuciak”] in view of the Merck Manual.

Siuciak discloses that it is known in the art that nerve growth factor (Col. 6, lines 16-31) is used for the treatment of depression as well as panic disorders (Col. 6, lines 44-65).

The Merck Manual discloses that the definition of depression (a unipolar) disorder falls under a broad class of mood or affective disorders (Page 1525). The Merck

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Manual also states that individuals with mixed anxiety-depression possess conditions of symptoms that have both anxiety and depression (page 1529) and that depressed patients are anxious and depressed, typically (page 1531). The Merck Manual specifically discloses to the skilled artisan that a patient with the condition of PMS is characterized, *inter alia*, by anxiety and depression (page 1932).

Although Siuciak is silent to the use of NGF to treat the psychological conditions of PMS, anxiety disorders, and panic attacks, Siuciak does in fact teach and provide the artisan with the necessary motivation to use nerve growth factor in the treatment of affective and anxiety disorders (Col. 6, lines 44-65).

Moreover, the determination of a specific range of a dosage having the optimum therapeutic index is well within the level of knowledge of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug while minimizing unwanted and/or adverse side effects as a matter of general practice. Hence, Siucuak in view of the Merck Manual make obvious the claimed subject matter.

Accordingly, one having ordinary skill in the art would have recognized that by treating depression and anxiety, one would also be treating and alleviating the symptoms of related conditions and ailments that have depression and anxiety as symptoms, namely anxiety disorders, PMS, and depression associated with menstruation and anxiety associated with panic attacks, most especially in view of the teaching of the Merck Manual.

In traversing the above rejection, Appellants argue that the Board should reverse the above final rejection, because (1) nerve growth factor is a different protein than

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BDNF, NT-3 and NT-4, known to have different properties; (2) the Merck Manual do not overcome the deficiency in Siuciak, because Merck Manual neither teach nor suggest the use of NGF for the treatment of any disease, let alone for the treatment of psychological disorders disclosed in the contemplated invention; and (3) the only motivation or suggestion to combine Siuciak with the Merck Manual to alleviate the symptoms of psychological disorders arises from disclosures of the present invention and therefore, constitute impermissible hindsight.

Importantly, Siuciak was an issued patent on the date to which the Appellants claim priority.

Siuciak teaches that “[t]he neurotrophin family *includes* brain-derived neurotrophic factor (BDNF), neurotrophin-3 (NT-3) and neurotrophin-4 (NT-4), all of which have recently been molecularly cloned and shown to be members of the nerve growth factor (NGF) family by virtue of their sequence homology” (Col. 2, lines 50-55)(emphasis added). The word “includes” implies that there are other members of the neurotrophin family in addition to the three listed, specifically. *See e.g. Mars Inc. v. H.J. Heinz Co.*, 377 F. 3d 1369, 1376 (Fed. Cir. 2004)(The word comprising is synonymous with the words including, containing, and characterized by, and all of these words are open-ended or inclusive and does not exclude additional, unrecited elements or agents).

Siuciak teaches that “[b]ased on the activity of neurotrophic factors, especially those members of the neurotrophin family ... applicants have discovered that the neurotrophins are useful for the treatment of depression” (Col. 4, lines 64-67).

To further bolster, rather than to establish the Appellee’s position, it is noted that the Appellants’ specification teaches that “[n]erve growth factor (NGF) [is] a prototypical

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neurotrophic factor and member of the neurotrophin family ... (Page 12, lines 27-28).

Furthermore, "there remains a desire to use NGF to remedy other neurological disorders ... [such as] depression, anxiety, [and] bipolar disorder" (Specification p. 13, lines 19-23).

It is unreasonable for the Appellants to argue that NGF illustrates the typical qualities of neurotrophic factors and members of the neurotrophin family and then to say that the teachings in Siuciak do not make the disclosure of the instant invention obvious, because it "does not teach the use of NGF which is a different protein for the treatment of depression and other psychological disorders" (Appellants' Remarks After Non-Final Rejection, p.7, ¶1). If NGF is a prototypical neurotrophic factor and a member of the neurotrophin family claimed to treat depression, just as the neurotrophins in Siuciak, it would go without saying that the teachings of Siuciak make the present invention obvious, particularly in view of the Merck Manual disclosure, as discussed, *infra*.

The requisite motivation to combine references is present, because although Siuciak is silent as to the use of NGF to treat the psychological conditions of PMS and panic attacks, explicitly, the same does teach the use of NGF to treat affective disorders and anxiety disorders. The Merck Manual merely defines affective and anxiety disorders more clearly to include the alleviation of symptoms of related conditions and ailments that have depression and anxiety as symptoms, namely anxiety disorders, PMS and panic attacks.

In view of the foregoing, the rejection that claims 1,2,4, 5, 8-18, and 20-24 are obvious over Siuciak in view of the Merck Manual should be sustained.

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(10) Response to Argument

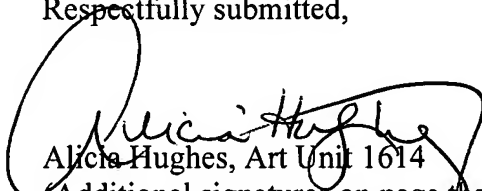
The responses have been included in the rejections above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Alicia Hughes", is written over the typed name and unit number.

Alicia Hughes, Art Unit 1614

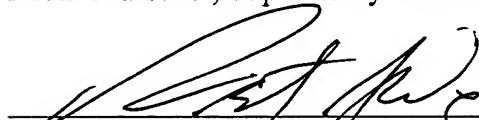
(Additional signatures on page that follows)

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Conferees:



Ardin Marschel, Supervisory Patent Examiner, Art Unit 1614



Robert Wax, Technology Center 1600 Quality Assurance Specialist